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10/589,562

08/16/2006

Klaus Abraham-Fuchs

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HARNESSE, DICKEY & PIERCE, P.L.C.

P.O.BOX 8910

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EXAMINER

PASS, NATALIE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/589,562 | Applicant(s) ABRAHAM-FUCHS ET AL. | |
| | Examiner Natalie A. Pass | Art Unit 3686 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 August 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application and amendment filed 16 August 2006. Claims 1-12 are pending. The Information Disclosure Statement filed 16 August 2006 has been entered and considered.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-12 are rejected under 35 U.S.C. §101.

A) As per claims 1-12, these appear to be directed toward a method or process of calculating a measure of the feasibility of a medical project. Based on Supreme Court precedent, and recent Federal Circuit decisions, the Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps. Thus, to qualify as a § 101 statutory process, the claim

should positively recite the other statutory class (the thing or product) to which it is tied, for example by identifying the apparatus that accomplishes the method steps, or positively recite the subject matter that is being transformed, for example by identifying the material that is being changed to a different state.

In the instant application, Appellant's method steps fail the first prong of the new Federal Circuit decision since they are not required to be tied to another statutory class and can be performed without the use of a particular apparatus. In particular, Applicant's claims do not recite who or what is performing the method steps. Furthermore, the method steps fail to unambiguously require transformation of underlying subject matter to a different state or thing. The mere manipulation and production of non-functional descriptive material (i.e., "patient data") is not a transformation because patient data is not statutory subject matter. Thus, claim 1 is non-statutory since it is not requisitely tied to another statutory class and does not requisitely transform underlying subject matter to a different state or thing. Dependent claims 2-12 merely add further details of the process recited in claim 1 without including any tie to another statutory category nor any transformation of subject matter into a different state or thing, and are therefore non-statutory as well.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 4-5, 7, 10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson et al. (2002/0002474).

(A) As per claim 1, Michelson teaches a method for calculating a measure of the feasibility of a medical project with acceptance criteria for patients, comprising:

- setting target criteria set for the project (Michelson; paragraph [0163]);
- selecting a “subject” (reads on “patient”) group including potential “subjects” (reads on “patients”), with the aid of the acceptance criteria, from a database containing “subject” (reads on “patient”) data of the “subjects” (reads on “patients”) (Michelson; paragraph [0184]); and
- evaluating the patient data of the patient group with the aid of the selected target criteria, and calculating the measure of the feasibility of the medical project (Michelson; paragraphs [0081], [0105]-[0106], [0166]).

(B) As per claims 2, 4-5, 7, 10, 12, Michelson teaches a method as analyzed and discussed in claim 1 above wherein

- the acceptance criteria are modified with the aid of the “subject” (reads on “patient”) data of the patient group (Michelson; paragraph [0011]);
- the “subject” (reads on “patient”) data of the patient group are used for carrying out the medical project (Michelson; paragraph [0177]); and
- a clinical study is verified as the medical project (Michelson; paragraphs [0081], [0085], [0088]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 6, 8-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson et al. (2002/0002474).

(A) As per claim 3, 6, Michelson teaches a method as analyzed and discussed in claim 1 above .

Michelson fails to teach a method wherein

a patient model is compiled with the aid of the patient data of the patient group; and
the acceptance criteria are modified with the aid of the patient model.

However Michelson teaches method wherein

a model is compiled with the aid of the investigator data of the investigator group
(Michelson; paragraph [0159]); Examiner interprets Michelson's teachings of a "ranking system which is a tool to help predict the success ... [...] ... " and in which "certain fields of the ... [...] ... database ... [...] ... are weighted based on one or more algorithms and where ... [the participant] ... is assigned a ranking value" and where "[t]he specific weighting algorithm can be used as a tool to predict performance ... [...] ... " to teach a form of compiling a model for predictions; and

the acceptance criteria are modified with the aid of the model (Michelson; paragraphs [0011]), [0159]-[0161]); Examiner interprets Michelson's teachings of "[t]he feasibility of the study can then be further explored by modifying the criteria" (Michelson; paragraph [0011]) and "the inventive system refines these rankings" (Michelson; paragraph [0161]) to teach a form of modifying the acceptance criteria with the aid of the model.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Michelson to include these limitations as applied to patients or "subjects" with the motivations of identifying "records of persons likely to be subjects eligible for the clinical study" and of evaluating "[t]he feasibility of the clinical study" and where the "feasibility of the study can then be further explored by modifying the criteria" (Michelson; paragraph [0011]).

(B) As per claims 8-9, 11, Michelson teaches a method as analyzed and discussed above wherein

the "subject" (reads on "patient") data of the patient group are used for carrying out the medical project (Michelson; paragraph [0177]); and

a clinical study is verified as the medical project (Michelson; paragraphs [0081], [0085], [0088]).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied references, Freedman U.S. Patent Application Publication Number 2003/0097291, Shah U.S. Patent Application Publication Number 2004/0093240, Klennart et al., U.S. Patent Application Publication Number 2004/0044547, McAlindon et al., U.S. Patent Number 7251609, Michelson et al., U.S. Patent Application Publication Number 2008/0133270, Briegs et al., U.S. Patent Number 7054823, teach the environment of evaluation of clinical trials.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Pass whose telephone number is (571) 272-6774. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 6:30 PM. The examiner can also be reached on alternate Fridays.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/N. A. P./
Examiner, Art Unit 3686
December 17, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686